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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/724,564	11/26/2003	Wayne Edward Beimesch	414130	9670
³⁰⁹⁵⁴ LATHROP & (7590 10/09/2007		EXAMINER	
2345 GRAND			ROGERS, DAVID A	
SUITE 2800 KANSAS CITY, MO 64108			ART UNIT	PAPER NUMBER
			2856	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

•	·	Application No.	Applicant(s)	
Office Action Summary		10/724,564	BEIMESCH, WAYNE EDWARD	
		Examiner	Art Unit	
		David A. Rogers	2856	
Period fo	The MAILING DATE of this communication app or Reply		orrespondence address	
VVHIC - Exte after - If NC - Failu Any	ORTENED STATUTORY PERIOD FOR REPLY CHEVER IS LONGER, FROM THE MAILING DANSIONS of time may be available under the provisions of 37 CFR 1.13 SIX (6) MONTHS from the mailing date of this communication. Poperiod for reply is specified above, the maximum statutory period were to reply within the set or extended period for reply will, by statute, reply received by the Office later than three months after the mailing ed patent term adjustment. See 37 CFR 1.704(b).	ATE OF THIS COMMUNICATION 36(a). In no event, however, may a reply be time will apply and will expire SIX (6) MONTHS from Cause the application to become ARANDONE.	N. hely filed the mailing date of this communication.	
Status				
2a) <u></u>	Responsive to communication(s) filed on 18 Second This action is FINAL . 2b) This Since this application is in condition for allowar closed in accordance with the practice under E	action is non-final. nce except for formal matters, pro		
Dispositi	on of Claims			
5)	Claim(s) 23-34 is/are pending in the application 4a) Of the above claim(s) is/are withdraw Claim(s) is/are allowed. Claim(s) 23-34 is/are rejected. Claim(s) is/are objected to. Claim(s) are subject to restriction and/or on Papers The specification is objected to by the Examiner The drawing(s) filed on 16 November 2003 is/are Applicant may not request that any objection to the or Replacement drawing sheet(s) including the correction The oath or declaration is objected to by the Examiner The oath or declaration is objected to by the	vn from consideration. relection requirement. re: a)⊠ accepted or b)□ objected or by consideration. drawing(s) be held in abeyance. See on is required if the drawing(s) is objected.	ected to. See 37 CFR 1.121(d).	
Priority u	inder 35 U.S.C. § 119			
12) <u> </u>	Acknowledgment is made of a claim for foreign All b) Some * c) None of: 1. Certified copies of the priority documents 2. Certified copies of the priority documents 3. Copies of the certified copies of the priorical application from the International Bureausee the attached detailed Office action for a list of	have been received. have been received in Application ity documents have been receive (PCT Rule 17.2(a)).	on No d in this National Stage	
2)	e of References Cited (PTO-892) e of Draftsperson's Patent Drawing Review (PTO-948) nation Disclosure Statement(s) (PTO/SB/08) No(s)/Mail Date	4) Interview Summary (Paper No(s)/Mail Da 5) Notice of Informal Pa 6) Other:	te	

DETAILED ACTION

Continued Examination Under 37 C.F.R. 1.114

1. A request for continued examination under 37 C.F.R. 1.114, including the fee set forth in 37 C.F.R. 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 C.F.R. 1.114, and the fee set forth in 37 C.F.R. 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 C.F.R. 1.114.

Claim Rejections - 35 U.S.C. § 103

- 2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
 - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 3. Claims 23-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over United States Patent 4,930,906 to Hemphill.

Official notice was taken in the previous office action that aluminum foil is a material that inherently does not release significant amounts of volatile organic compounds (VOCs). The applicant did not traverse this official notice. Rather, the applicant agrees with this statement. See page of the response filed 9/18/07:

With respect to Claim 23, Applicant recognizes that the Examiner's official notice that aluminum foil is a material that does not release significant amounts of volatile organic compounds (VOCs).

Therefore, this is now factual prior art.

With regard to claims 23 and 25 the phrase "for measuring the volatile organic compounds of a substance" is not being affording any patentable weight. This phrase amounts to how the kit is to be used and does change or otherwise impact the structure of the kit. As the applicant is fully aware a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

With regard to claim 24 the phrase "for measuring the volatile organic compounds of a substance produced in a process system having emissions" is not being affording any patentable weight. This phrase amounts to how the kit is to be used and does change or otherwise impact the structure of the kit. As the applicant is fully aware a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

Hemphill discloses an enclosed bag (reference item 10) and having instructions (reference items 18 and 20). Hemphill's bag, being foldable, is also inherently collapsible in that it is formed of thin plies of materials. The enclosed bag also has a maximum fill line (reference item 19). This bag, when sealed, would have a headspace above the maximum fill line. Hemphill's bag is formed of a multiply construction. The inner layer (reference item 13) is formed of polyethylene. The outer layer (reference item 13) is formed of polyethylene. The outer layer (reference item 13) is formed of paper.

According to Hemphill the outer paper layer is provided to "protect an individual from being burned by the hot grease." See column 4 (lines 26-28). It is considered obvious to eliminate the outer paper layer when protection from hot grease is not an issue. For example, the bag could be used to store cooler materials, including cold grease, so that burning is not design consideration. See also MPEP §2144.0 4:

A. Omission of an Element and Its Function Is Obvious If the Function of the Element Is Not Desired

Ex parte Wu, 10 USPQ 2031 (Bd. Pat. App. & Inter. 1989) (Claims at issue were directed to a method for inhibiting corrosion on metal surfaces using a composition consisting of epoxy resin, petroleum sulfonate, and hydrocarbon diluent. The claims were rejected over a primary reference which disclosed an anticorrosion composition of epoxy resin, hydrocarbon diluent, and polybasic acid salts wherein said salts were taught to be beneficial when employed in a freshwater environment, in view of secondary references which clearly suggested the addition of petroleum sulfonate to corrosion inhibiting compositions. The Board affirmed the rejection, holding that it would have been obvious to omit the polybasic acid salts of the primary reference where the function attributed to such salt is not desired or required, such as in compositions for providing corrosion resistance in environments which do not encounter fresh water.). See also In re Larson,

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340 F.2d 965, 144 USPQ 347 (CCPA 1965) (Omission of additional framework and axle which served to increase the cargo carrying capacity of prior art mobile fluid carrying unit would have been obvious if this feature was not desired.); and In re Kuhle, 526 F.2d 553, 188 USPQ 7 (CCPA 1975) (deleting a prior art switch member and thereby eliminating its function was an obvious expedient).

With regard to claim 23 (lines 5-7) the claimed bag is formed of materials that do not release significant amounts of VOCs. A review of the applicant's written description shows that the sole disclosed embodiment for the bag is one formed of an aluminum inner layer and a polyethylene outer layer. Therefore, aluminum and polyethylene are materials that do not release significant amounts of VOCs. The bag of Hemphill, when the paper layer is omitted, is also formed of aluminum and polyethylene and, therefore, will also be formed of materials that do not release significant amounts of VOCs.

With regard to claim 24 (lines 6-8) the claimed bag is formed of materials that can be safely stored at the exit temperature of a process system. A review of the applicant's written description shows that the sole disclosed embodiment for the bag is one formed of an aluminum inner layer and a polyethylene outer layer. Therefore, aluminum and polyethylene are materials that can be safely stored at the exit temperature of a process system. The bag of Hemphill, with or without the paper layer, is also formed of aluminum and polyethylene and, therefore, will also be formed of materials that can be safely stored at the exit temperature of a process system.

With regard to claim 25 (lines 5-7) the claimed bag consists of two layers, one being an impermeable inner layer and one being a polymer outer layer. A

review of the applicant's written description shows that the sole disclosed embodiment for the bag is one formed of an aluminum inner layer and a as discuss laber polyethylene outer layer. The bag of Hemphill, without the paper layer, will consist of two layers wherein the inside layer (reference item 13) is the vapor impermeable aluminum layer and the outer layer (reference item 11) is made of a polyethylene polymer.

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With regard to claim 32 (lines 3-5) the claimed bag has a wall consisting of an inner liner and an outer liner that do not release significant amounts of VOCs. A review of the applicant's written description shows that the sole disclosed embodiment for the bag is one formed of an aluminum inner layer and a polyethylene outer layer. Therefore, aluminum and polyethylene are materials that do not release significant amounts of VOCs. The bag of Hemphill, without the paper layer will have a wall consisting of two liners wherein the inside aluminum liner (reference item 13) and the outer polyethylene liner (reference item 1). The bag of Hemphill, when the paper layer is omitted, will also be formed of materials that do not release significant amounts of VOCs.

In all Hemphill teaches a kit that meets the structural limitations of the applicant's claims. Hemphill, however, does not teach specific instructions with regard to sampling and analyzing.

In the precedential decision *In re Ngai*, 70 USPQ 2d 1862, the Court of Appeals for the Federal Circuit (CAFC) reviewed a situation clearly analogous to

the applicant's claims. In Ngai *et al.* a kit was claimed was claimed as follows (emphasis added):

19. <u>A kit</u> for normalizing and amplifying an RNA population, <u>said kit comprising</u> <u>instructions describing the method of claim 1 and a premeasured portion of a reagent selected from the group consisting of</u>. oligo dT biotinylated primer, T7 RNA polymerase, annealed biotinylated primers, streptavidin beads, polyadenyl transferase, reverse transcriptase, Rnase H, DNA pol I, <u>buffers</u> and nucleotides.

The CAFC analyzed Ngai et al.'s claim 19 and determined that the elements that formed the kit included a premeasured portion of reagent and instructions on how to use the reagent. The cited prior art was a kit having a 10X buffer and specific instructions on how to use the 10X buffer. In referring to *In re Gulack*, 703 F.2d 1381 [217 USPQ 401] (Fed. Cir. 1983), the CAFC stated:

"This case [Ngai], however, is dissimilar from Gulack. There the printed matter and the circularity of the band were interrelated, so as to produce a new product useful for "educational and recreational mathematical" purposes. Here, addition of a new set of instructions into a known kit does not interrelate with the kit in the same way as the numbers interrelated with the band. In Gulack, the printed matter would not achieve its educational purposes without the band, and the band without the printed matter would similarly be unable to produce the desired result. Here, the printed matter in no way depends on the kit, and the kit does not depend on the printed matter. All that the printed matter does is teach a new use for an existing product. As the Gulack court pointed out, "[w]here the printed matter is not functionally related to the substrate, the printed matter will not distinguish the invention from the prior art in terms of patentability." Id. If we were to adopt Ngai's position, anyone could continue patenting a product indefinitely provided that they add a new instruction sheet to the product."

The CAFC affirmed the Board of Patent Appeals and Interferences (BPAI) and concluded that Ngai et al.'s claimed kit was anticipated by the prior art (the 10X buffer with instructions), despite the fact that Ngai et al.'s claim 1 method was distinct from the instructions in the prior art. In fact, the method

of claim 1 was determined to be patentable over the prior art. The CAFC further concluded that Ngai et al.'s instructions merely taught how to use the reagent component of the kit (the 10X buffer). Specifically, the CAFC concluded:

"All that the printed matter does is teach a new use for an existing product."

and

"He [Ngai] is not, however, entitled to patent a known product by simply attaching a set of instructions to that product."

In the present application the instructions merely teach a different use for a known sealable bag. The applicant's claimed enclosed bag does not depend on the claimed instructions in order to function; i.e., the instructions do not enable the bag to hold a sample. Likewise, the claimed instructions do not depend on the bag in order to instruct someone how to sample. Therefore, the applicant's instructions do not enable any sealable bag from holding any material and only describe a process to store a sample in the bag and then to sample the headspace of the bag.

The applicant's claims for a kit comprising a bag and instructions to use the bag is clearly analogous to Ngai et al.'s kit having a known reagent (the 10X buffer) and instructions that taught how to use the reagent. The applicant's arguments with regard to how their instructions are not taught by the prior art, and, therefore, there can be no anticipation are also similar to those proffered by Ngai et al. However, both the BPAI and the CAFC unequivocally and unambiguously disagreed with that argument.

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the teachings of Hemphill in order to provide appropriate instructions on how to use the bag based on the fact that the applicant's kit is known or otherwise obvious in the art as evidenced by Hemphill, and further in view of the CAFC's decision in *In re Ngai*.

Response to Arguments

4. Applicant's arguments with respect to claims 23-34 and filed 09/18/07 have been fully considered but are moot in view of the new ground(s) of rejection. The applicant's amendment caused new grounds of rejection; e.g., rejection under 35 U.S.C. 103 vice a rejection under 35 U.S.C. 102. The changes to the claims, namely the recitation of either consisting of two layers or comprising layers that do not emit significant amounts of VOCs, has been addressed above.

Conclusion

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to David A. Rogers whose telephone number is (571) 272-2205. The examiner can normally be reached on Monday - Friday (0730 - 1600). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Hezron E. Williams can be reached on (571) 272-2208. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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6. Information regarding the status of an application may be obtained from

the Patent Application Information Retrieval (PAIR) system. Status information

for published applications may be obtained from either Private PAIR or Public

PAIR. Status information for unpublished applications is available through

Private PAIR only. For more information about the PAIR system, see

http://pair-direct.uspto.gov. Should you have questions on access to the

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9197 (toll-free). If you would like assistance from a USPTO Customer Service

Representative or access to the automated information system, call 800-786-

9199 (IN USA OR CANADA) or 571-272-1000.

/David Rogers/ Examiner - Group Art Unit 2856